

### **REMARKS**

Applicants have received and carefully reviewed the Decision on Appeal mailed March 29, 2011. Claims 18, 27, and 33 have been amended. Support for the amendments and new claim is found in the specification, claims, and drawings as originally filed. No new matter has been added. Reconsideration and withdrawal of the rejections are respectfully requested.

### **Request to Reopen Prosecution**

The Decision on Appeal mailed March 29, 2011 designated the affirmance as a new ground of rejection pursuant to 37 CFR § 41.50(b). In response, Applicants hereby elect to reopen prosecution with the above amendments to the claims. Applicants respectfully request consideration of the above amendments and the following remarks.

### **Rejection under 35 U.S.C. § 103(a)**

Claims 18-23, 25-27, 30-36, 38-41, and 46-48 are rejected as being unpatentable over Foley (US 5,792,044) in view of Ash (WO 83/03189) and Zdeblick (US 6,206,922). Independent claim 18, as amended, recites:

18. (currently amended) A system for performing a fixation procedure at a spinal location within a patient, comprising:  
at least two fasteners adapted to be fixed to two adjacent vertebrae;  
an elongate body having a proximal end and a distal end and defining a length between the proximal and distal ends such that the proximal end can be positioned outside the patient and the distal end can be positioned inside the patient adjacent the spinal location, the elongate body having an outer surface and an inner surface, the inner surface defining a passage extending between the proximal and distal ends sized to permit passage of the at least two fasteners therethrough; and  
a fixation element sized to pass through the passage of the elongate body and configured to engage the at least two fasteners;  
wherein the elongate body is actuatable between a first configuration sized for insertion into the patient and a second configuration wherein the cross-sectional area of said passage at a first location is greater than the cross-sectional area of said passage at a second location, wherein the first location is distal to the second location; wherein the cross-sectional area of said passage at said first location is sized to permit visualization of two fasteners fixed to two adjacent vertebrae; wherein the elongate body is configured such that the passage provides unobstructed access from the proximal end to the distal end when in the second configuration.

None of Foley, Ash, or Zdeblick appears to teach or suggest such a structure. The Examiner acknowledges that Foley fails to disclose a system comprising an elongate body that is actuatable as claimed. Zdeblick do not appear to teach an elongate body that is actuatable as recited in the claim. Ash is cited as teaching a device having an elongated body expandable at the distal end to provide viewing and operation room. The Examiner asserts that it would have been obvious to manufacture the device of Foley with an expandable distal end in view of Ash to provide viewing and operation room. Applicants respectfully disagree.

Ash appear to teach a device comprising an elongated external tube 12 with retraction levers 28 at the distal end and an internal conduit 34 with an actuator means 32, a viewing conduit 24, and an access channel 88 all within the external tube 12. See page 5, lines 17-35, page 9, lines 24-26, and FIGS. 1-2. Ash thus appear to teach a device in which a passage defined by an inner surface contains various structural elements, including internal conduit 34, viewing conduit 24, and access channel 88. Applicants note that the passage defined by the inner surface of external tube 12 appears to be the only structure in Ash in which "the cross-sectional area of said passage at a first location is greater than the cross-sectional area of said passage at a second location, wherein the first location is distal to the second location." The passages defined by the internal conduit 34, viewing conduit 24, and access channel 88 do not appear to have the claimed cross-sectional area and thus cannot be considered to be the claimed "passage." Ash do not appear to teach a device with an actuatable distal region in which the passage provides unobstructed access. Thus, even if one were to combine Foley, Ash, and Zdeblick, one would not arrive at the structure recited in the claim. Further, there is no motivation for one of ordinary skill in the art to modify the devices of Foley, Ash, and/or Zdeblick to achieve such a structure. Reconsideration and withdrawal of the rejection are respectfully requested.

Independent claim 27, as amended, recites:

27. (currently amended) A system for performing a fixation procedure at or near the spine of a patient, said system comprising:

an access device adapted to define a passage from a location outside of the patient to a location at or near the spine of the patient, the access device being at least partially actuatable between a first configuration and a second configuration, wherein the passage of the access device in the second configuration has a cross-sectional area at a first location that is greater than the cross-sectional area of said passage at a second location, wherein the first location is distal to the second location; and

a vertebral fixation assembly configured to fix two adjacent vertebrae, the vertebral fixation assembly adapted to be delivered through the passage of the access device, the vertebral fixation assembly comprising a plurality of vertebral screws and a fastener adapted to engage each of the vertebral screws;

wherein the cross-sectional area at the first location is sized to permit visualization of two or more screws fixed to at least two adjacent vertebrae; wherein the access device is adapted to be actuated from the first configuration to the second configuration with an application of force to an inner surface of the passage, the access device adapted to remain in the second configuration upon removal of said force.

None of Foley, Ash, or Zdeblick appears to teach or suggest such a structure. Ash is cited as teaching an actuatable device. Ash does not appear to teach a device in which “the access device is adapted to be actuated from the first configuration to the second configuration with an application of force to an inner surface of the passage, the access device adapted to remain in the second configuration upon removal of said force,” as recited in claim 27. Ash teaches:

As shown in the embodiment of FIGURES 1-3 the actuator means 32 includes a mechanical linkage 46 mechanically interconnecting the internal conduit 34 and the levers 28. As the internal conduit 34 is moved proximally with respect to the external tube 12, the mechanical linkage 46 extends outwardly to urge the distal ends 44 levers 28 apart. Alternatively, the levers could be urged apart as the internal conduit 34 is moved distally...

Alternatively as shown in FIGURES 4-6 the actuator means 132 can include camming means 154 carried by the external tube 112 and viewing system or internal conduit 134. The camming means 154 includes a bead 156 carried by the internal conduit 134 which cooperates with a tab 158 on each lever 128 so that the distal ends 144 of the levers are urged apart as the conduit 134 is moved longitudinally with respect to the external tube 112.

Emphasis added; see page 7, lines 8-16 and 18-27, and FIGS. 1, 2, and 5. Ash thus appear to teach a device in which the force on the levers 28 provided by the mechanical linkage 46 is needed to keep the levers in the expanded position. Further, because Ash teach the mechanical linkage interconnecting the internal conduit 34 and the levers 28 it appears maintaining the levers in the expanded position requires continual force. Ash does not appear to teach an expandable device in which the expanded configuration is maintained upon removal of the expansion force. A combination of Foley, Ash, and Zdeblick thus does not appear to teach the claimed structure. Additionally, because Ash appears to specifically teach a device in which force on the levers

appears to be necessary to keep the levers in the expanded configuration, there is no motivation for one of ordinary skill in the art to modify the references to achieve the claimed structure. Reconsideration and withdrawal of the rejection are respectfully requested.

Independent claim 33, as amended, recites:

33. (currently amended) A system for performing a fixation procedure at a spinal location within a patient, said device comprising:

an access device having a proximal end and a distal end and a length defined between the proximal and distal ends such that the proximal end can be positioned outside the patient and the distal end can be positioned inside the patient adjacent the spinal location, wherein the access device includes a passage extending there through, the access device being expandable from a first configuration to a second configuration, wherein the passage of the access device in the second configuration has a cross-sectional area at the distal end of the device that is greater than a cross-sectional area at the proximal end of the device, said passage being sized for delivery of instruments to perform the procedure at the spinal location, the access device being configured to expand to the second configuration with an expansion tool positioned in the passage, the access device configured to remain in the second configuration upon removal of the expansion tool from the passage;

at least two threaded fasteners sized for delivery through said passage at least when the access device is in its second configuration, the fasteners being configured to be fixed to adjacent vertebrae, wherein said cross-sectional area at the distal end of the device in the second configuration is sized to permit visualization of the at least two threaded fasteners fixed to at least two adjacent vertebrae; and

a fixation element sized for delivery through the passage of the access device.

None of Foley, Ash, or Zdeblick appears to teach or suggest such a structure. Ash is cited as teaching an actuatable device. Ash does not appear to teach a device “being configured to expand to the second configuration with an expansion tool positioned in the passage, the access device configured to remain in the second configuration upon removal of the expansion tool from the passage,” as recited in the claim. Ash appears to teach a device in which actuator means 32 connected between an internal conduit 34 and levers 28 provide the mechanical linkage 46 to move levers 28. These elements appear to be part of and connected to the elongate external tube 12 and are thus not removable. See page 7, lines 2-33, and FIGS. 1, 2, and 5. Ash further teaches advantages of this expansion structure:

The movement of the internal conduit 34 and viewing system 18 relative to the external tube 12 to operate the tissue retraction levers 28 is particularly

advantageous. It is unnecessary to have a separate lever operating connections extending through the tube which would waste space and increase the size of the tube and the hole which must be made in the patient. There is also greater reliability and safety for the patient without such separate connections.

See page 9, lines 13-22. Ash thus appears to teach advantages provided by a device in which the distal levers 28 are expanded by a linkage that is part of the overall device. As such, it appears that if one were to remove the expansion system of internal conduit 34, actuator means 32, and mechanical linkage 46 from the external tube 12, there would be no structure to keep the levers 28 in an expanded configuration. Ash does not appear to teach a device that is configured to remain in an expanded configuration upon removal of an expansion tool. Thus, even if one were to combine Foley, Ash, and Zdeblick, one would not arrive at the structure as claimed. Further, there is no rational reason for one of ordinary skill in the art to modify Ash to achieve the claimed structure. Reconsideration and withdrawal of the rejection are respectfully requested.

Additionally, Foley appears to teach away from the claimed structure and from any combination with Ash. In the Decision on Appeal, the Board stated,, on page 8, “[a] warning against use of an element, rather than omission of mention of the element, is required to find teaching away. *Para-Ordnance Manufacturing v. SGS Importers International Inc.*, 73 F.3d 1085, 1090 (Fed Cir. 1995).” Applicants submit that Foley provides such a warning against use of a device such as Ash, which creates a more invasive surgical procedure. Foley teaches:

Prior surgical techniques for each of these procedures has evolved from a grossly invasive open surgeries to the minimally invasive techniques represented by the patents of Kambin and Shapiro. However, in each of these minimally invasive techniques, multiple entries into the patient is required. Moreover, most of the prior minimally invasive techniques are readily adapted only for a posterolateral approach to the spine. The devices and instruments of the present invention have application in an inventive surgical technique that permits each of these several types of surgical procedures to be performed via a single working channel. This invention can also be used from any approach and in other regions besides the spine.

Emphasis added; see column 9, line 66 through column 10, line 11. Foley, which was filed in 1996, appears to teach that their minimally invasive techniques, involving a fixed diameter cannula, are preferred to the previous, invasive surgical techniques. Applicants submit that one of ordinary skill in the art would understand that the 1983 procedure of Ash, involving retraction

and expansion of a surgical site, would be considered more invasive than the procedure using the fixed diameter cannula of Foley. Similarly, the claimed system includes an elongate body with an outer surface that retracts tissue at the spinal location. Foley appears to teach away from such a modification to their device. Foley thus appears to provide the necessary warning against use of the expanding device of Ash, in order to maintain the minimally invasive technique specifically taught by Foley as having numerous advantages.

For example, Foley teaches advantages provided by their single fixed diameter cannula:

Another advantage provided by the single working channel cannula 20 of the present invention, is that the cannula can be readily positioned over an appropriate target tissue or bone, to thereby move the working space as necessary for the surgical procedure. In other words, since the working channel cannula 20 is freely situated within the patient's skin and tissue, it can be manipulated so that the working space beneath the cannula 20 is more appropriately centered over the target region of the spine. Repositioning of the cannula 20 can be performed under fluoroscopic guidance. Alternatively, the cannula may be fitted with position sensing devices, such as LEDs, to be guided stereotactically. As the cannula is being repositioned, the surgeon can also directly visualize the spine through the viewing element 50.

See column 12, lines 3-15. Foley already teaches a system which provides viewing and operation room to fuse two adjacent vertebrae, thus there is no motivation or reason to modify Foley as asserted by the Examiner. Foley teaches:

as depicted in FIG. 1, a device 10 is provided for use in percutaneous surgery which includes an elongated cannula 20 having a first inner diameter  $D_1$  and an outer diameter  $D_0$  sized for percutaneous introduction into a patient. The cannula 20 also includes a distal working end 21 and an opposite proximal end 22. The cannula defines a working channel 25 between the ends 21, 22 having a second diameter  $d_2$  equal to the first inner diameter  $D_1$  sized for receiving a tool therethrough.

Emphasis added; see column 5, lines 37-46 and FIG. 1. Foley also teaches:

The insertion of vertebral fixation elements can also be accomplished through the device 10. In this type of procedure, an incision can be made in the skin posterior to the location of the vertebra at which the fixation element is to be implanted. Implementing the steps shown in FIG. 10, the cannula 20 can be positioned through the incision and tissue directly above the particular location on the vertebra to be instrumented. With the optics extending through the working channel, an insertion tool holding the vertebral fixation element can be projected through the cannula 20 and manipulated at the vertebra. In one specific

embodiment, the fixation element can be a bone screw. The working channel 25 has a diameter that is large enough to accept most bone screws and their associated insertion tools.

...

The device 10 can also be used to prepare a site for fusion of two adjacent vertebrae, and for implantation of a fusion device or material.

...

A fusion device, such as a bone dowel, a push-in implant or a threaded implant can then be advanced through the working channel of device 10 and into the prepared bore at the subject disc space. In some instances, the preparatory steps involve preparing the vertebral endplates by reducing the endplates to bleeding bone. In this instance, some aspiration and irrigation may be beneficial. All of these procedures can be conducted by tools and instruments extending through the working channel cannula 20 and under direct vision from the viewing element 50.

Emphasis added; see column 15, lines 3-15, 35-37 and 57-67. Foley thus appears to teach a system for insertion of either vertebral fixation elements, such as bone screws, or fusion implants through the fixed diameter device 10. Foley also appear to teach the insertion of the screws or implants as being done under direct vision from a viewing element. Zdeblick appears to teach insertion of fusion device 10 through a fixed diameter outer sleeve 76. See column 11, lines 3-16 and FIG. 11c. Both Foley and Zdeblick appear to teach insertion of fusion devices through fixed diameter devices, and Foley provide a warning against a modification such as that found in Ash, thus there is no motivation for one of ordinary skill in the art to modify Foley and/or Zdeblick with Ash to provide a device with an expandable distal end. The Examiner's reasons for combining Foley and Zdeblick with Ash is "to provide viewing and operation room and to fuse two adjacent vertebrae." However, as discussed above, Foley and Zdeblick already appear to teach devices that provide viewing and operation room to fuse adjacent vertebrae. In view of the specific teachings of Foley and Zdeblick, the motivation to combine their teachings with Ash appears to be (1) because their combination is within the skill of the ordinary artisan; (2) found in Appellant's specification; of (3) merely because the references could be combined. All of these possible motivations to combine Foley, Zdeblick and Ash are improper.

**Conclusion**

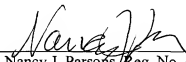
Reconsideration and reexamination are respectfully requested. It is submitted that, in light of the above remarks, all pending claims are now in condition for allowance. If a telephone interview would be of assistance, please contact the undersigned attorney.

Respectfully submitted,  
THOMAS W. DAVISON

By his Attorney,

Date: \_\_\_\_\_

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Nancy J. Parsons, Reg. No. 40,364  
SEAGER, TUFTE, & WICKHEM, LLC  
1221 Nicollet Avenue, Suite 800  
Minneapolis, Minnesota 55403-2420  
Telephone: (612) 677-9050  
Facsimile: (612) 359-9349